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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,917	ELLIOTT ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11-20,23,26-32,34,36 and 44-55* is/are pending in the application.

4a) Of the above claim(s) *1,2,11,14-20,23,26-32,34,36 and 44-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,12 and 13* is/are rejected.

7)☒ Claim(s) *3-7,12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0607*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election, with traverse, of Invention II(SEQ ID NO: 13) in their response of January 27, 2009 is acknowledged. The elected invention is directed to a polynucleotide encoding the polypeptide of SEQ ID NO: 13. Applicants' traversal is based on the argument that examination of all of Groups II, IV, V, IX, XIV, and XV would not be an undue burden. However, examining all of said groups represents an undue burden because the groups have a separate status in the art and require different fields of search as well as consideration under 35 USC 101 and 112. The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-7, 11-20, 23, 26-32, 34, 36, and 44-55 are pending. Claims 1, 2, 11, 14-20, 23, 26-32, 34, 36, and 44-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 3-7, 12, and 13 are hereby examined.

Oath

The Oath of April 27, 2007 is objected to because it is not signed by all inventors.

Priority

The priority date granted for the instant invention is April 30, 2003, the filing date of US 60/467,491, which disclosed the elected invention.

Claims-Objections

Claims 3-7, 12, and 13 are objected to for being dependent from non-elected claims.

Claims 3-7, 12, and 13 are objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Claims 3-7, 12, and 13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The specification fails to assert or teach a specific and substantial function for the protein set forth by SEQ ID NO: 13, as encoded by SEQ ID NO: 56. Tables 2 and 3 teach that the polypeptide of SEQ ID NO: 13 has homology with proteins having a wide variety of activities, including a G-protein signaling, serine protein kinase activity, receptor tyrosine kinase activity, G-protein coupled receptor activity, and pleckstrin domain activity. Said teachings of homology are not an assertion of activity or utility for the protein of SEQ ID NO: 13. Even if said teachings of homology were an assertion of activity or utility, which they are not, the specification fails to provide any evidence that the protein of SEQ ID NO: 13 has any of G-protein signaling, serine protein kinase activity, receptor tyrosine kinase activity, G-protein coupled receptor activity, or pleckstrin domain activity. In addition, the skilled artisan would believe that more, likely than not, a single protein would not have all said activities.

As stated in the specification, the proposed utilities for SEQ ID NO: 56 are: therapeutics, diagnostics, production of SEQ ID NO: 13 for making antibodies, and identification of modulators. Each of these utilities is an application which would apply to every member of the general class of materials of nucleic acids and/or is a use only for further research to determine a use for SEQ ID NO: 56 or the protein encoded thereby. As such, these asserted utilities are not

specific (for those applicable to all nucleic acids) or not substantial because the use of SEQ ID NO: 56 therein is only potential and not in currently available in practical form.

Therefore, Claims 3-7, 12, and 13 are rejected under 35 U.S.C. 101 because the claimed invention lacks a specific, substantial, and credible patentable utility.

Claims 3-7, 12, and 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 3, the phrase "naturally occurring" in parent Claim 1(k) renders the Claim 3 indefinite. It is unclear whether said phrase encompasses polypeptides endogenous to mutated organisms. The skilled artisan would not know the metes and bounds of the recited invention. Claims 6 and 7, as dependent from Claim 3, are indefinite for the same reason.

Claims 3-7, 12, and 13 are rendered indefinite for improper antecedent usage as follows.

For Claim 3, the phrase "a polypeptide of claim 1" should be corrected to "the polypeptide of claim 1".

For Claim 4, the phrase "a polypeptide of claim 2" should be corrected to "the polypeptide of claim 2".

For Claim 5, the phrase "An isolated polynucleotide of claim 4" should be corrected to "The isolated polynucleotide of claim 4".

For Claim 6, the phrase "a polynucleotide of claim 3" should be corrected to "the polynucleotide of claim 3".

For Claim 7, the phrase "a recombinant polynucleotide of claim 6" should be corrected to "the recombinant polynucleotide of claim 6".

For Claim 12(k), the phrase "a polynucleotide of a)" should be corrected to "the polynucleotide of a)".

For Claim 13, the phrase "a polynucleotide of claim 12" should be corrected to "the polynucleotide of claim 12".

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Even if the above rejection under 35 U.S.C. 101/112 were not made, the following rejection would be made.

Claims 3, 6, 7, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for any polynucleotide encoding any naturally-occurring polypeptide having at least 90% identity with SEQ ID NO: 13 or comprising

any fragment of SEQ ID NO: 56. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 3, 6, and 7 are so broad as to encompass any polynucleotide encoding any naturally-occurring polypeptide having at least 90% identity with SEQ ID NO: 13. Claim 13 is so broad as to encompass any polynucleotide comprising any fragment of SEQ ID NO: 56 of at least 60 contiguous residues. It is noted that by use of "comprising" language, Claim 13 encompass polynucleotides, wherein the desired activity is not derived from the sequence homologous to SEQ ID NO: 56.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural

and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired unrecited activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 3, 6, and 7, which encompasses all polynucleotides encoding any naturally-occurring polypeptide having at least 90% identity with SEQ ID NO: 13. The specification does not support the broad scope of Claim 13, which encompasses all polynucleotides comprising any fragment of SEQ ID NO: 56 of at least 60 contiguous residues. The specification does not support the broad scope of Claims 3, 6, 7, and 12 because the specification does not establish: (A) the desired activity of all encompassed polynucleotides or the encoded polypeptides; (B) regions of the protein structure which may be modified without affecting the desired activity; (C) the general tolerance of the desired activity to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying

any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotides with an enormous number of modifications of SEQ ID NO: 56 or encoding any polypeptide with an enormous number of amino acid modifications of SEQ ID NO: 13. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Tang et al, 2001. Tang et al teaches a polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 56, wherein the polypeptide encoded by Tang's polynucleotide has 94% homology with SEQ ID NO: 13 herein. Tang et al further teaches

vectors that comprise their polynucleotide and fragments of their polypeptide. Therefore, Claims 3, 6, 7, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Tang et al, 2001.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652